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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

In re CONNETICS SECURITIES LITIGATION	Case No. C 07-02940 SI **CLASS ACTION** **LEAD PLAINTIFF'S OPPOSITION TO THE MOTION TO DISMISS FILED BY DEFENDANTS CONNETICS CORP., JOHN L. HIGGINS, LINCOLN KROCHMAL, C. GREGORY VONTZ, AND THOMAS G. WIGGANS** Date: October 19, 2007 Time: 9:00 a.m. Courtroom: 10 Judge: Hon. Susan Illston

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The Teachers' Retirement System of Oklahoma (the "Lead Plaintiff") respectfully submits this opposition to the motion to dismiss (referred to herein as the "Motion" or "Mot.") filed by defendants Connetics Corp. ("Connetics or the "Company"), John L. Higgins ("Higgins"), Lincoln Krochmal ("Krochmal"), C. Gregory Vontz ("Vontz"), and Thomas G. Wiggans ("Wiggans").

I. INTRODUCTION

This is a securities class action against Connetics and certain of its top officers for violations of §§ 10(b), 20(a) and 20A of the Exchange Act of 1934 and SEC Rule 10b-5. Connetics was a pharmaceutical company that developed and marketed dermatological products to treat various skin conditions, including acne. In 2002, the Company announced its acquisition of the rights to Velac Gel, a purportedly "safe and effective" acne treatment that had yet to undergo the required testing for, or to obtain approval from, the Food and Drug Administration ("FDA").

The Complaint sets forth in detail how defendants concealed Velac's spectacular failure in FDA-mandated laboratory tests.[1] Defendants misled investors about Velac's prospects for FDA approval, falsely reported that the Company was poised to capture a large part of the acne medication market, and concealed that Velac caused cancer at such an alarming rate that even a panel of experts who Connetics itself had selected concluded that no drug exhibiting such cancer-causing properties had ever been approved by the FDA.

Not only did defendants make false and misleading statements about the safety and approvability of Velac, its "new" product, but they also issued false financial statements regarding sales of current products. At the specific direction of Higgins, Wiggans and Vontz, Connetics intentionally "sold" excess inventory to its three main distributors – a deceptive practice called "channel stuffing" – and also understated Connetics' reserves for the inevitable return of excess product in violation of Generally Accepted Accounting Principles ("GAAP").

[1] "Complaint" refers to the Amended Consolidated Class Action Complaint For Violation of the Federal Securities Laws. "¶_" refers to paragraphs in the Complaint. Throughout, all emphasis is added and internal citations are omitted unless otherwise noted. "Ex." refers to those exhibits attached to defendants' request for judicial notice.

Ultimately, Connetics was forced to restate its financial results in the wake of a Securities and Exchange Commission ("SEC") investigation. Such a restatement is an admission that the financial statements were false when made.

As a result of defendants' false and misleading statements, Connetics securities traded at artificially-inflated prices between January 27, 2004 and July 9, 2006 (the "Class Period"), reaching as high as $29 per share. When the truth was revealed in a series of partial disclosures beginning on April 26, 2005, the Company's stock price collapsed to $7.76. Investors, including Lead Plaintiff, suffered substantial losses. While defendants contend that Lead Plaintiff lacks standing because it did not own stock on one day during the Class Period, June 13, 2005, defendants ignore that Lead Plaintiff purchased shares during the Class Period and held them through numerous partial disclosures and thus incurred losses. *See VeriSign, Inc. Sec. Litig.*, 2005 WL 88969 (N.D. Cal. Jan. 13, 2005) (rejecting contention that plaintiffs lacked "standing" for misrepresentations made after plaintiff's last stock purchase).

In short, the Complaint is a well-pleaded document, fully complying with Supreme Court and Ninth Circuit precedent and the pleading requirements of the Private Securities Litigation Reform Act of 1995 ("PSLRA").

In their motion, defendants mischaracterize the Complaint, literally re-writing certain allegations, and attempt to rely on extraneous material to resolve factual disputes at the pleading stage. They do so for a transparent reason: setting forth the allegations accurately would confirm that the Complaint pleads the very detail that defendants claim is absent. The Complaint identifies defendants' false statements, explains why they were false and misleading, raises a strong inference of defendants' scienter, and explains how investors suffered losses when the truth was eventually revealed.

II. SUMMARY OF THE CONSOLIDATED COMPLAINT

The Complaint sets forth the undisclosed facts known to Connetics insiders as they promoted Velac and issued false financial statements. Wiggans was Connetics' Chief Executive Officer; Vontz was Connetics' Executive Vice President and Chief Commercial Officer, Chief Operating Officer and President; Higgins acted as Chief Financial Officer and Executive Vice

President, Finance and Administration and Corporate Development; and, Krochmal was Connetics' Executive Vice President of Research and Product Development. ¶¶19-22. Each was a member of Connetics' Management Executive Committee, responsible for "the overall direction, strategy and operations of Connetics, including, among other things, corporate financial performance, commercial performance, research, development and product operations performance[,]" and are collectively referred to herein as the "Insider Defendants." ¶¶23-24. Each Insider Defendant made misleading statements to the market and is liable under §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. § 78j(b).[2]

Beginning as early as 2002, Connetics touted the importance of Velac, its new acne medication that would capture a large portion of the $1 billion U.S. acne medication market. ¶¶40-51. To obtain FDA approval of Velac, Connetics was required to assess the drug's carcinogenicity. ¶¶37-38. To test carcinogenicity, defendants selected from among the FDA-required studies the transgenic mouse study (the "Mouse Study" or "Tg.AC study"). Defendants Yaroshinsky, Vontz and Krochmal personally oversaw the Mouse Study and, according to a witness in a position to know such matters, reported the results to defendants Wiggans and Higgins. ¶¶52-55. By no later than June 2004, Connetics had obtained the results of the FDA-required study which revealed Velac caused cancer at alarming rates, resulting in 89 out of 160 mice that were treated with Velac developing cancerous skin tumors. ¶56. On June 28, 2004, after obtaining the adverse results of the Mouse Study, Connetics convened its own panel of toxicology experts who informed Connetics that they did not know of any drug that exhibited a "positive dermal" similar to Velac that ever had been approved by the FDA. ¶57.

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[2] Defendant Alexander J. Yaroshinsky ("Yaroshinsky") served as Vice President of Biostatics and Clinical Operations for Connetics during the Class Period and was responsible for analyzing the results of drug development studies and preparing regulatory submissions to the FDA – including Velac. ¶¶25, 55, 68. At all relevant times, he was an employee of Connetics and his knowledge is attributable to the Company. *See In re CV Therapeutics, Inc. Sec. Litig.*, 2004 WL 1753251, at *10 (N.D. Cal. Aug. 5, 2004). Yaroshinsky engaged in illegal insider sales while in possession of material, non-public information concerning Velac and provided material, non-public information to an individual not employed by the Company, defendant Victor E. Zak ("Zak"). ¶¶86-95. Lead Plaintiff addresses Yaroshinsky and Zak's motion to dismiss in a separate opposition filed concurrently herewith.

Rather than disclose the results of the Mouse Study, defendants concealed the truth and continued to make false and misleading statements concerning Velac. ¶¶199, 202, 203, 208, 219, 224, 225, 234, 236, 238-239, 242-246, 255, 257-259, 261-262. For instance, during a Company conference call on January 25, 2005, defendant Vontz mischaracterized the results of the Company's testing of Velac by stating:

> [W]e're very confident in the data set that we've got. We believe it's one of the strongest data sets for an acne products [sic] submitted to the FDA. And we're obviously very excited to launch it.

¶245. These and other statements misled investors into believing FDA approval of Velac was imminent and the drug highly profitable. For instance, on September 29, 2004, an analyst from Jefferies & Company, Inc. reported: "We believe Velac gets approved with minimal obstacles and becomes a significant growth driver for Connetics on its path to becoming a leading acne therapy." ¶63. And, as late as April 26, 2005, an analyst with Buckingham issued a report indicating Velac would be a "fundamental catalyst" for the Company going forward. ¶72. At the same time defendants concealed the results of the Mouse Study and made misleading statements concerning the safety, efficacy and likelihood of FDA approval of Velac, defendants sold millions of dollars of Connetics stock. ¶¶165-167.

On April 13, 2005, Connetics held a non-public conference call with the FDA's Executive Carcinogenicity Assessment Committee ("ECAC"), who told Connetics what the Company's own toxicology experts had previously stated: the Mouse Study was a serious impediment for the approval of Velac for market and sale in the United States. ¶¶68-69. The ECAC also told Connetics: (i) "[Velac] may be a tumor promoter or a carcinogen"; and (ii) "this is a ***serious*** issue for a topical product for the treatment of acne." ¶69.

On April 26, 2005, Connetics finally issued a press release that ***partially*** disclosed certain aspects of the issues raised by the FDA. ¶74. The Company never disclosed the actual results of the Mouse Study and, moreover, falsely stated the conclusions reached by the Company's own toxicology panel:

> The Company carefully analyzed the results with a panel of leading toxicologists and experts in this model. The experts advised the Company that the transgenic mouse model is known to have limitations, and the experts concluded that the positive response was the result of a limitation of the model. The advice of these

> experts is supported by other products which had a positive finding but were ultimately approved based on additional work in other animal models."

¶75. Defendants also falsely reassured investors, stating the Company planned to provide the FDA additional "information so this issue can be resolved and enable us to launch Velac on schedule" and noting the Company was still "forecasting the launch of Velac in the third quarter." ¶¶261-262. Defendants also failed to disclose that: (i) the FDA told Connetics that "this is a serious issue for a topical product for the treatment of acne"; (ii) Connetics had been aware of the "positive dermal" in the Mouse Study for nearly a year; and (iii) Connetics' hand-picked panel of toxicology experts told the Company that they were aware of no drug exhibiting a "positive dermal" such as Velac that had ever been approved by the FDA. ¶76. As a result of defendants' false statements on April 26, the market continued to believe that Velac would be approved and its stock price, while declining 17%, remained artificially inflated. ¶¶80-81.

On June 13, 2005, the Company revealed that the FDA issued a formal non-approval letter for Velac because it was "unsafe for use" as indicated by the Company's Mouse Study a year earlier. ¶¶82-83. After the Company's disclosure, the Company's stock price tumbled an additional 27% on top of its earlier decline on April 27th. ¶85.

Between the time of the Company's conference call with the FDA on April 13th and the Company's eventual disclosure on June 13th that Velac would not be approved, defendants Higgins and Vontz sold over $437,000 in Connetics stock at inflated prices and defendants Zak and Yaroshinsky profited in excess of $1.5 million. ¶¶165, 167.

At the same time that defendants were making false and misleading statements concerning its "new" blockbuster acne medication, they were also falsifying Connetics' financial statements with respect to the sales and revenues of its existing products. Connetics sold products not to doctors or patients, but to large distributors who acted as middlemen and could return products or obtain rebates and chargebacks based on certain conditions. ¶¶101-106. Connetics booked revenue when items were shipped to the distributors and was supposed to take reserves to cover returns, rebates and chargebacks. ¶¶107-108. During the Class Period, in an effort to meet quarterly forecasts, the Insider Defendants intentionally shipped product to

distributors in excess of what the distributors then needed – a practice known as channel stuffing. ¶109. Confidential witnesses confirm that defendants Wiggans, Higgins and Vontz personally oversaw and personally directed the Company's channel stuffing activities. ¶¶112-118. Defendants' intentional channel stuffing caused Connetics' accruals for rebates, chargebacks and returns to be materially understated, which, in turn, materially overstated the Company's earnings and caused its publicly-filed financial statements to violate GAAP. ¶119. By injecting excessive inventory into the distribution channel, Connetics and the Insider Defendants knew that significant amounts of Connetics' products would remain unsold through the expiration date and, therefore, would be returned to Connetics. ¶119.

Ultimately, the SEC launched another investigation into matters at Connetics (in addition to the SEC's on-going investigation of the Company's Velac-related fraud activities) – this one focusing on channel stuffing activities. The Company was forced to restate its prior published financial results and announce its previously published financial results "should no longer be relied upon." ¶¶98, 120, 121, 126, 133-145.[3] In that announcement, however, defendants falsely reassured investors they had already accounted for a reduction in inventory levels. ¶¶123-124. As a result of defendants' partial disclosure of Connetics' true financial condition, Connetics' stock dropped and investors suffered damages. ¶¶122, 125.[4] Finally, on July 10, the last day of the Class Period, Connetics disclosed it would report materially lower earnings for the second quarter and full-year 2006 because the Company had to "reduce wholesaler inventory" that had been built up through the Company's channel stuffing activities. ¶127. Connetics' stock price plummeted 34% in one day on heavy trading volume. After the July 10 announcement, analysts quickly questioned "management's lack of transparency" and pointed out that on May 3rd

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[3] Contrary to defendants' insinuations (Mot. at 6), there is no evidence that the SEC has ended its investigation or in any way exculpated Connetics and its officers and directors.

[4] The Company made its official announcement on May 3, 2006 after the close of trading, however the news leaked into the market during the trading day on May 3, 2006. This is apparent from the over 700% increase in trading volume from May 2, 2006 (242,800) to May 3, 2006 (1,780,300), and the Company's stock decline from a close on May 2, 2006 of $15.27 to a close on May 3, 2006 of $13.76. *See* Mot. Ex. 41.

defendants had falsely stated that efforts to reduce inventory were already incorporated into their prior guidance. ¶128.

III. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 12(b)(6), a district court may dismiss a complaint only if it fails to state a claim upon which relief can be granted. The question is not whether a plaintiff will prevail in the action, but whether it is entitled to offer evidence in support of its claim. *See Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974), *overruled on other grounds, Davis v. Scherer*, 468 U.S. 183 (1984). In answering this question, the Court must "accept all factual allegations in the complaint as true." *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2509 (2007). "The Court should not use judicial notice to generate an evidentiary record and then weigh evidence – which plaintiffs have not had the opportunity to challenge – to dismiss plaintiffs' complaint." *In re Network Equip. Tech., Inc. Litig.*, 762 F. Supp. 1359, 1363 (N.D. Cal. 1991). To do so would improperly convert the motion to dismiss into a motion for summary judgment.[5]

Rather than accept as true the well-pleaded allegations, defendants' Motion relies upon factual inferences and assertions not found in the Complaint nor properly judicially noticed, rendering defendants' arguments more akin to a summary judgment brief than an assessment of the Complaint as actually drafted. *See, e.g.*, Mot. at 3-10. Moreover, the Motion mischaracterizes the Complaint's allegations. *See In re SupportSoft Sec. Litig.*, 2005 WL 3113082, at *6 (N.D. Cal. Nov. 21, 2005) (denying motion because "[t]he problem with defendants' position . . . is that it miscasts the allegations in plaintiffs' complaint."). "Plaintiffs are the master of their complaint and neither this Court nor the defendant[s] have the right to

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[5] *See In re NPS Pharm., Inc.*, 2007 WL 1976589, at *2 (D. Utah July 3, 2007) (striking exhibits to motion to dismiss where defendants "made misleading statements regarding the safety, efficacy, potential FDA approval, and potential market size of [a drug] in violation of §10(b)"); *In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 995 (S.D. Cal. 2005) (same); *Faulkner v. Beer*, 463 F.3d 130, 134 (2d Cir. 2006) (vacating dismissal of complaint because district court considered "materials outside the record"); *In re Applied Micro Circuits Corp. Sec. Litig.*, 2002 U.S. Dist. LEXIS 22403, at *8 (S.D. Cal. Oct. 4, 2002) (refusing to consider "extrinsic evidence").

redraft the complaint. . . . Defendants must take the Complaint[] as [it is] written." *In re Initial Pub. Offering Sec. Litig.*, 241 F. Supp. 2d 281, 332-333 (S.D.N.Y. 2003).

Defendants' mischaracterizations are demonstrated by these illustrative examples:

Defendants' Recitation of the Allegations	**The Complaint's Actual Allegations**
"[T]he Amended Complaint admits that the ultimate conclusion of the expert panel was that the result of the preclinical study was due to limitations in the Tg.AC model." Mot. at 17, n.12 (citing ¶¶257, 261).	The Complaint alleges defendants issued a ***false*** press release on 4/26/05 stating "experts concluded that the positive response was the result of a limitation of the model." ¶257. *See also* ¶261 (same).
"As acknowledged in the Amended Complaint, however, the transgenic mouse model has significant limitations and does not always or reliably predict risks to humans." Mot. at 6 (citing ¶56).	"[A]ccording to a National Institutes of Health research paper published in October 2002, transgenic mouse models 'made the 'correct' calls (positive for carcinogens; negative for noncarcinogens) 77-81%' of the time." ¶56.
"The Company was also aware of other products that had a similar positive finding in Tg.AC mice but nevertheless had been approved by the FDA. For example, benzoyl peroxide . . . " Mot. at 7 (citing ¶¶257, 261 (and Ex. 1)).	No allegation in the Complaint supports defendants' assertion that other products had ***similar*** positive findings in Tg.AC mice but nevertheless were approved. Defendants refer the Court to statements in ¶257 and ¶261 (and Ex. 1), which the Complaint alleges are ***false***.

Contrary to the well-pleaded allegations, and despite the fact that 89 out of 160 mice that were treated with Velac developed cancerous skin tumors, defendants also erroneously contend "Connetics had reason to be optimistic . . . [because of] the limitations of and number of 'false positives' associated with the Tg.AC model." Mot. at 18 (citing ¶¶56, 76, 257, 261). There is no allegation in the Complaint that even remotely supports defendants' contention that the Tg.AC model results in "false positives," let alone a material amount of "false positives." Rather, the Complaint references a finding that "transgenic mouse models 'made the 'correct' calls (positive for carcinogens; negative for noncarcinogens) 77-81%' of the time." ¶56. While defendants' Motion attempts to dispute the accuracy of Tg.AC models (an issue for experts), the fact is that defendants themselves chose this study to satisfy the FDA's requirements. ¶54. Moreover, defendants can point to no facts indicating that the results of the Company's Mouse Study are simply the result of "false positives."[6] Here, the Mouse Study results were not merely

[6] Rather, the Complaint references a finding that "transgenic mouse models 'made the 'correct' calls (positive for carcinogens; negative for noncarcinogens) 77-81%' of the time." ¶56. False positive results occur when a statistically significant number of mice (all living in controlled

statistically significant, they were unprecedented. ¶56. Defendants cite no authority – nor should the Court take judicial notice of any such purported authority – indicating that defendants had reason to be "optimistic" concerning the results of the Mouse Study.

Defendants take further improper liberties with the Complaint, by making repeated references to Connetics' own May 14, 2002 press release filed with the SEC on Form 8-K. Defendants cite their press release for the factual assertion that the Mouse Study was not troublesome because "clinical studies in Europe in more than 700 patients . . . demonstrated that Velac gel was both 'safe and as effective as leading topical treatments."' Mot. at 6, 8, 18 (citing Ex. 8). The results of the purported European studies in 2002 (two years before the Class Period even begins) are not before the Court. They are irrelevant to the FDA-required studies that demonstrated Velac's carcinogenicity, and there is no indication that the European studies even tested for carcinogenicity. The Court should not take judicial notice of these disputed facts. *See* Lead Plaintiff's Opposition to Defendants' Motion for Judicial Notice at Section II.B.2.

Defendants likewise ask the Court to go beyond the four corners of the Complaint and decide their motion based on their submission of 41 exhibits consisting of over 700 pages. By way of example, defendants assert that "the very same FDA division director making the determination on Velac had previously approved dermatology products, such as Clobex, notwithstanding similar 'safety' concerns of the FDA's advisors." Mot. at 8, n.4 (citing Exs. 32 and 33). No allegation in the Complaint supports defendants' factual contention that there were "***similar*** 'safety' concerns" with Clobex. This characterization is unsupported and, in any event, an area for expert testimony. Indeed, a close reading of the exhibits relied on by defendants demonstrates that the safety concerns were not at all "similar."[7] Similarly, defendants allege that

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environments) randomly grow tumors for reasons unexplainable by the testing procedures. The fact that the Tg.AC model does not always render a conclusive finding correctly predicting carcinogenicity does not imply that the Tg.AC model reaches false positives.

[7] Clobex posed concerns regarding teratogenic potential and "a relatively high risk for HPA axis suppression when used at maximal conditions of labeled use" that both could be addressed by "labeling agreed to by the sponsor." Ex. 32 at 2, 7. By contrast, Velac posed high risks of cancer. ¶4. Teratogens and carcinogens are completely different. Moreover, there is no

"[c]onsistent with industry norms, it was not Connetics' practice to disclose interim communications with the FDA." Mot. at 5. "Industry norms" and "Connetics' practice" are neither alleged nor judicially noticeable, and are subject to expert testimony. Indeed, defendants' characterizations are inconsistent with the Complaint's allegations concerning the Company's practice and the April 26, 2005 disclosure of "interim" communications with the FDA. ¶¶72-74.

Defendants also improperly attempt to rewrite the Complaint's allegations concerning the Company's GAAP violations by citing ***disputed*** facts stated in Connetics' SEC filings. *See* Lead Plaintiff's Opposition to Defendants' Motion for Judicial Notice at Section II.B. (explaining that the content of SEC filings may not be judicially noticed for the truth of the facts represented therein). Relying upon Connetics' restatement in its Form 10-K/A filed after the Class Period on July 25, 2006, defendants assert: "Connetics' reserve estimates were impacted by inaccurate and inconsistent inventory level reports provided by its three main wholesale customers . . . Once Connetics began to receive accurate reports . . ., [it] took steps to increase its reserves." Mot. at 10, n.5. Defendants' explanation of the cause of the Company's inadequate reserves is both far fetched (*i.e.*, its three main separate customers simultaneously delivered inaccurate reports) and at direct odds with the Complaint's detailed allegations of defendants' intentional channel stuffing and awareness of excessive inventory levels. ¶¶109-120. Taking judicial notice of defendants' explanation for the restatement – which is contrary to the Complaint's allegations – would "allow officers and directors of corporations to exercise an unwarranted degree of control over whether they are sued, because they must agree to a restatement of the financial statements." *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72, 83 (1st Cir. 2002). Defendants' recitation of their own SEC filings does not render such statements true or the "facts" judicially noticeable. Under Ninth Circuit law, the Court may ***not*** take "judicial notice of disputed facts stated in public records." *Lee v. City of Los Angeles*, 250 F.3d 668, 690 (9th Cir. 2001); *see also In re Adaptive Broadband Sec. Litig.*, 2002 WL 989478, at *20 (N.D. Cal. Apr. 2, 2002) (same as to SEC filings).

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indication the teratogenic potential of Clobex was at all comparable to the extreme carcinogenicity of Velac, which caused cancer at alarming rates.

IV. THE COMPLAINT STATES A CLAIM FOR VIOLATIONS OF § 10(b)

A complaint states a claim under § 10(b) of the Exchange Act when it alleges: (1) a false statement or omission (2) of material fact (3) made with scienter (4) on which the plaintiff justifiably relied (5) that proximately caused the alleged loss. *See Binder v. Gillespie*, 184 F.3d 1059, 1063 (9th Cir. 1999). The Complaint readily satisfies these pleading requirements.[8]

A. The Complaint Specifically Identifies Defendants' Material False Statements And Omissions

A complaint sufficiently pleads falsity where it includes (1) each statement or omission alleged to have been misleading; (2) the reason or reasons why the statement or omission is misleading; and (3) all facts on which that belief is formed. *See Desaigoudar v. Meyercord*, 223 F.3d 1020, 1023 (9th Cir. 2000). Here, the Complaint identifies defendants' false statements and omissions, explains why each was false and misleading when made, and alleges particularized facts supporting each allegation.

1. Defendants' False Statements And Omissions Regarding Velac

Defendants made false statements and omissions regarding the safety and efficacy of Velac, assuring investors of Velac's pending FDA approval and projecting large revenues for the product, while concealing the results of an FDA-required laboratory study indicating that Velac was carcinogenic (*i.e.*, 89 out of 160 mice treated with Velac had developed cancerous skin tumors), that the Company had been informed by an expert panel that the panel knew of no drug that exhibited a similar result and was approved by the FDA, and that the FDA itself had indicated that Velac was unlikely to receive approval. ¶¶56-57, 68-70.

The Complaint alleges that defendants concealed that Velac caused cancer at alarming rates while affirmatively making misleading statements indicating that FDA approval was a foregone conclusion. For instance, during the Company's January 25, 2005 conference call, defendants stated, among other things: (i) "[W]e are confident that we will be successful in this market with our acne franchise, and in particular, with Velac"; (ii) "With the expected approval of

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[8] Defendants do not dispute that the Complaint sufficiently pleads reliance. *See* ¶¶336-341.

Velac in the middle of this year . . . ."; (iii) "We forecast enjoying a full year of Velac sales . . . ."; (iv) "[W]e're very confident in the data set that we've got. We believe it's one of the strongest data sets for an acne products [sic] submitted to the FDA. And, we're obviously very excited to launch it." ¶¶242-245. Each of the statements was misleading because defendants failed to disclose the true, material fact that Velac caused cancer at alarming rates and that they had been informed by their own experts that FDA approval was unlikely. ¶¶52-57.

In determining whether defendants' statements were misleading, "[t]he test is a 'reasonable investor' test. It asks whether an investor who had been reasonably diligent . . . would have been misled." *Kiyashka v. Iasiaworks, Inc.*, 2002 U.S. Dist. LEXIS 9554, at *20 (N.D. Cal. May 13, 2002). Here, no "reasonable investor" could have accurately assessed the likelihood of Velac obtaining FDA approval because defendants concealed that Velac caused cancer at alarming rates, and that they had been told by their very own experts (and later the FDA itself) that FDA approval was unlikely. Defendants' Velac-related "statements cannot be evaluated without regard to what [defendants] omitted to say." *In re InterMune, Inc. Sec. Litig.*, 2004 WL 1737264, at *6 (N.D. Cal. July 30, 2004).

Defendants incorrectly assert they had no duty to disclose the truth about the danger of Velac, the Mouse Study results, or the fact that FDA approval was unlikely. Mot. at 21. Under Rule 10b-5, however, it is improper "to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they are made, not misleading." 17 C.F.R. § 240.10b-5(b); *see also S.E.C. v. Fehn*, 97 F.3d 1276, 1290 n.12 (9th Cir. 1996) (duty to disclose is a "general one, and arises whenever a disclosed statement would be 'misleading' in the absence of the 'disclosure of [additional] material facts'"). Defendants were obligated to disclose the truth because they: (i) made misleading statements concerning Velac's safety and FDA approval throughout the period after the study results were made known to them (*see, e.g.*, ¶¶60, 65, 75, 78, 208, 219, 224-225, 234, 236, 238, 242-246, 257); (ii) made filings with the SEC that

should have disclosed material facts impacting the Company (*see, e.g.*, ¶¶65, 255); and (iii) the defendants sold shares after the study was made known to them (*see* ¶165).[9]

In re CV Therapeutics, Inc., Sec. Litig., 2004 WL 1753251 (N.D. Cal. Aug. 5, 2004), is instructive. There, defendants allegedly made misleading statements concerning the safety and efficacy of their new drug and mischaracterized the likelihood of receiving FDA approval. The complaint alleged that clinical study results and communications with the FDA raised serious concerns regarding the drug's safety and efficacy. *Id*. at *1-2. Like here, defendants argued "defendants' statements concerning the efficacy and safety of [the drug] and its ultimate FDA approval had a 'reasonable basis,' making the statements not false or misleading when made." *Id.* at *4. Rejecting defendants' argument, the Court explained: "At a later stage, the issue of the reasonableness of defendants' belief in their statements will arise again; for now, the complaint has pled fraud with adequate particularity." *Id.* at *6. Defendants attempt to distinguish *CV Therapeutics*, asserting that defendants in this action "never publicly discussed preclinical test results or discussions with the FDA." Mot. at 21 n.17. That is untrue. Defendants misleadingly described the Company's conference call with the FDA's ECAC. ¶¶74-79. Moreover, defendants made statements concerning test results and FDA approval of Velac. *See, e.g.*, ¶245 ("[W]e're very confident in the data set that we've got. We believe it's one of the strongest data sets for an acne products [sic] submitted to the FDA. And we're obviously very excited to launch it."). *CV Therapeutics* is directly on point.

Defendants attempt to dispute the materiality of the Mouse Study, asserting "courts have dismissed securities fraud claims based on a defendant's alleged failure to disclose adverse test

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[9] *See Shaw v. Digital Equip. Corp.*, 82 F.3d 1194, 1202 n.3 (1st Cir. 1996) (there are at least "three situations that could give rise to a duty to disclose material facts: (i) when an insider trades in the company's securities on the basis of material nonpublic information; (ii) when a statute or regulation requires disclosure; and (iii) when the company has previously made a statement of material fact that is false, inaccurate, incomplete, or misleading in light of the undisclosed information"). Numerous authorities recognize defendants' obligation to disclose the material, non-public information known to them. *See, e.g., United States v. O'Hagan*, 521 U.S. 642 (1997) (corporate insiders must disclose material information or abstain from trading). *In re Carter-Wallace, Inc. Sec. Litig.*, 150 F.3d. 153, 157 (2d Cir. 1998), cited by defendants (Mot. at 19) is inapposite. Unlike *Carter*, here, defendants had statistically significant scientific evidence that Velac cause cancer. ¶¶56-57.

results relating to a new drug where (as here) ***reasonable minds could differ on the significance of the results***." Mot. at 19, n.14. The Complaint, however, more than sufficiently alleges the results of the Mouse Study were "significant" or material; the well-pleaded facts establish that even defendants' own panel of experts informed them that they "did not know any drug that exhibited a 'positive dermal' similar to Velac that ever had been approved by the FDA."[10] Moreover, defendants ignore the standard for assessing materiality of an undisclosed fact on a motion to dismiss in this circuit. "It would be premature for this court to evaluate the actual materiality of defendants' omissions, because the materiality of an omission is a question reserved for a jury unless 'reasonable minds could not differ' on the adequacy of the disclosure and the question is appropriate for resolution as a matter of law."[11] Here, defendants argue only that "reasonable minds could differ on the significance" of the Mouse Study results. The Court rejected a similar argument in *In re Amylin Pharm., Inc. Sec. Litig.*, 2002 WL 31550051 (S.D. Cal. Oct. 10, 2002) *recons. denied*, 2003 WL 21500525 (S.D. Cal. May 1, 2003). In upholding the Complaint, the *Amylin* court rejected defendants' argument that FDA concerns could be "explained by different interpretations of the same clinical results" and were not indicative of scienter. 2002 WL 31550051, at *6.

Defendants also assert that "courts have held that a defendant cannot be held liable for securities fraud based on optimistic projections of FDA approval ***even where (unknown to investors) the FDA itself has raised concerns*** about the approvability of the drug." Mot. at 18 (emphasis in original) (citing *In re MedImmune, Inc. Sec. Litig.*, 873 F. Supp. 953, 966 (D. Md.

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[10] ¶57. This allegation is well pleaded on the basis of the SEC's complaint (paragraph 18), which states "the panel convened by Connetics reported that ***it*** was unaware of any drug exhibiting a 'positive dermal,' similar to Velac Gel, that had been approved by the FDA." *See* Ex. D to Yaroshinsky's request for judicial notice. Ignoring the actual Complaint itself, defendants assert that "plaintiff provides no specifics with respect to this alleged statement by ***a member*** of the expert panel," and then defendants attempt to rewrite the Complaint to add: "the ultimate conclusion of the expert panel was that the result of the preclinical study was due to limitations in the Tg.AC model." Mot. at 17, n.12. The ***panel*** (not one member) concluded Velac was likely not to be approved. ¶57. Both of defendants' assertions find ***no*** support in the Complaint or the volumes of improperly cited documents referenced by defendants' Motion.

[11] *In re CornerStone Propane Partners, L.P. Sec. Litig.*, 355 F. Supp. 2d 1069, 1086 (N.D. Cal. 2005); *see also In re DDi Corp. Sec. Litig.*, 2005 WL 3090882, at *11 (C.D. Cal. July 21, 2005).

1995)). Defendants' contention is against the great weight of authority holding to the contrary. For instance, in *Amylin*, 2003 WL 21500525, at *8 n.3, the court rejected the holding of *MedImmune*: "The court is not bound by *MedImmune* and disagrees with this holding. If a defendant states that it believes or expects that the FDA will approve its drug but has information tending to seriously undermine the accuracy of its statement, the statement is actionable." *Id.* (citing *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1113 (9th Cir. 1989)); s*ee also In re Sepracor, Inc., Sec. Litig.*, 308 F. Supp. 2d 20, 34 n.9 (D. Mass. 2004) (same). This Court has likewise declined to follow *MedImmune* and rejected defendants' recitation of the law.[12]

Defendants also assert that the Complaint has not "pleaded facts to show that Connetics' April 26, 2005 disclosures concerning its recent communications with the FDA's advisory committee (the ECAC) regarding the preclinical study were materially misleading . . . ." Mot. at 21-22. The ECAC told Connetics, but defendants failed to publicly disclose, that Velac "may be a tumor promoter or a carcinogen" and that "this is a serious issue for a topical product for the treatment of acne." ¶¶69, 76, 77. Defendants' April 26, 2005 partial disclosure also failed to disclose that Connetics' own hand-picked panel of toxicology experts was aware of no drug exhibiting a "positive dermal" such as Velac that had ever been approved by the FDA. *See* ¶76; *compare* ¶57 *with* ¶257. Moreover, as explained in the accompanying opposition to the motion to dismiss of Yaroshinsky and Zak, these defendants immediately traded short following the

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[12] *See CV Therapeutics*, 2004 WL 1753251, at *8-9. Defendants also cite *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212 (S.D. Cal. 2001), and *Noble Asset Mgmt. v. Allos Therapeutics, Inc*., 2005 WL 4161977 (D. Colo. Oct. 20, 2005). *Noble* relies upon *MedImmune* and is equally flawed. Moreover, in *Noble* plaintiffs did not specify the materiality of any purported "concerns" raised by the FDA; here, the concerns raised by the Tg.AC study were clearly material. Moreover, in *Noble* the "FDA did not reject the [drug] application, but rather classified it as 'approvable.'" *Id*. at *13. Here, Velac was flatly rejected. Finally, *DeMarco* does not stand for the proposition defendants assert. In *DeMarco*, the FDA did not raise any concerns about the drug until a meeting that occurred on "***the last day of the Class Period***" and therefore defendants could not have made any misrepresentations about the FDA's concerns. 149 F. Supp. 2d at 1216, 1224-25. Moreover, *DeMarco* is further distinguishable because, "[a]fter the close of the Class Period, the FDA approved" the drug in question thereby demonstrating defendants' one statement concerning the likelihood of approval was not without basis. *Id*. at 1216, 1232. Here, unlike *DeMarco*, Velac never was approved.

April 26 announcement – further confirmation that they knew additional negative information was yet to come. *See* ¶¶86-95.

2. Defendants' Admittedly False Financial Statements

The Complaint details how defendants not only made false statements and omissions regarding their purportedly future product (Velac), but throughout the Class Period they also made false statements regarding the sales and revenues from their current products. The Complaint details how each of the Company's financial statements issued during the Class Period were not prepared in compliance with GAAP. ¶¶137-145. "[F]inancial statements that are not prepared in conformity with [GAAP] are presumed to be misleading and inaccurate." *Goldstein v. MCI Worldcom*, 340 F.3d 238, 249 (5th Cir. 2003) (citing SEC Regulation S-X, 17 C.F.R. § 210.4-01(a)(1)); *see also* ¶138 (same).

The Complaint alleges the amount the Company misstated various reported metrics making up Connetics' financial statements during each quarter and yearly reporting period, and the specific accounting rules that were violated. ¶¶133-145. Further, the Complaint pleads details concerning the Company's practice to ship product prior to customers' need for the product, thereby increasing the likelihood the product would be returned and the necessity for increasing the Company's reserves, and the identities of those involved in the practice. ¶¶101-120. Defendants have admitted that during the Class Period, the Company's financial statements were not in compliance with GAAP, and have restated the Company's financial statements to reflect this. ¶¶130-136. Where, as here, the restatement is coupled by admissions that the restatement was due to earlier errors, the falsity of the restated financial statements is sufficiently pled. *See In re Nat'l Golf Props. Sec. Litig.*, 2003 WL 23018761, at *5 (C.D. Cal. Mar. 18, 2003) ("By restating these financials . . . Defendants essentially admit that the statements . . . were false."); *see also* ¶¶131, 138 (citing SFAS 16 and APB Opinion No. 20 (restatements are only permitted, and are required, for material accounting errors that existed at the time the financial statements were prepared)).

3. The Complaint's Allegations Are Corroborated By Eight Confidential Witnesses

The Complaint includes detailed allegations based on myriad sources, including defendants' own statements and press releases, the Company's restatement, the SEC investigation and complaint, analyst reports, and counsel's investigation, including accounts from eight confidential witnesses. Instead of directly addressing the Complaint's detailed allegations, defendants attempt to create a "mini-trial" over the credibility of the witnesses, whose accounts further corroborate other detailed allegations in the Complaint (and each other). Mot. at 33. In the Ninth Circuit, "[n]aming sources is unnecessary so long as the sources are described 'with sufficient particularity to support the probability that a person in the position occupied by the source would possess the information alleged' and the complaint contains 'adequate corroborating details.'" *In re Daou Sys. Inc., Sec. Litig.*, 411 F.3d 1006, 1015 (9th Cir. 2005). In *Daou*, the complaint satisfied these requirements where it "describe[d] the confidential witnesses with a large degree of specificity," "number[ed] each witness and describ[ed] his or her job description and responsibilities," and "[i]n some instances, plaintiffs provide[d] the witnesses' exact title and to which Daou executive the witness reported." *Id.* at 1016. Here too, the Complaint includes this detailed information with sufficient particularity to support the probability that a person in his/her position would possess the information alleged. It describes the confidential sources with specificity, identifying each witness numerically and describing his or her job description and responsibilities, and what and how the witness knew the information alleged. In most instances, the Complaint also provides the witnesses' exact title and identifies the time-frame employed by Connetics. *See, e.g.*, ¶¶53-55, 112-118, 147.

For example, the Complaint identifies Confidential Witness 1 ("CW1") as a "former employee of Connetics' Strategic Market Planning group who was employed at Connetics from 2002 through April 2006." ¶53. It further explains that CW1 "was directly involved in the forecasting process for more than three years (including throughout the Class Period)," and would assist in preparing initial annual forecasts and personally present them to defendants Wiggans, Higgins and Vontz in October of each year. ¶113. The Complaint describes the meetings CW1 attended, how defendant Wiggans regularly instructed CW1 to increase the

forecasts so that they were in line with Wall Street's expectations for Connetics' future sales and how Wiggans reprimanded CW1 because the 2005 forecast was too low. Facts attributed to CW1 are corroborated by Confidential Witness 3 ("CW3"), who is identified as "a former Regional Sales Director who worked at Connetics for more than eight years and throughout the entire Class Period." ¶55. CW3 attended certain of the same meetings as CW1 and, as Regional Sales Director, knew that the amount of products shipped (and therefore "sold") to distributors during the Class Period regularly exceeded the number of prescriptions that were being written for the products. CW3 also explained how, despite knowing that the inventory was too high, defendants Wiggans, Higgins and Vontz directed that even more product be shipped. ¶¶55, 112, 114, 115, 116, 118, 147. The other confidential witnesses – all identified, at a minimum, by job title and time-frame employed at Connetics – further confirm and corroborate the accounts of CW1 and CW3, and other allegations in the Complaint. ¶¶53-55, 112-118, 147.[13]

Defendants' reliance upon the out-of-circuit decision in *Higginbotham v. Baxter Int'l, Inc.*, 2007 WL 2142298 (7th Cir. July 27, 2007), is unavailing, as it does not address the standard in the Ninth Circuit, which standard continues to apply after the *Tellabs* decision.[14] Since *Tellabs*, courts have continued to accept as true – as they must – allegations based on witness accounts in finding a strong inference of scienter.[15] Moreover, unlike the confidential witnesses in *Higginbotham*, each of the confidential witnesses here worked directly for Connetics and was

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[13] ¶¶53, 55, 113, 114(i)-(iv), 118. These allegations belie defendants' argument that the confidential witnesses are only referenced variously as a "manager" and "territory manager" and that the Complaint does not detail witnesses' job responsibilities. Mot. at 34 n.27.

[14] *See In re InfoSonics Corp. Sec. Litig.*, 2007 WL 2301757, at *7 (S.D. Cal. Aug. 7, 2007) (applying *Daou* analysis to confidential witnesses after the June 21, 2007 *Tellabs* decision); *In re Lattice Semiconductor Corp. Sec. Litig.*, 2006 WL 538756, at *18 (D. Or. Jan. 3, 2006) (rejecting defendants' argument that the district court's decision in *Higginbotham* (later affirmed by the Seventh Circuit) changes the analysis).

[15] *See, e.g., In re NPS Pharm., Inc. Sec. Litig.*, 2007 WL 1976589, at *6. Indeed, even the outlying opinion in *Higginbotham* acknowledges that allegations based on confidential witnesses may support scienter, but only that such allegations must be "discounted." *Higginbotham*, 2007 WL 2142298, at *2-3; *see also id.* at *2 (recognizing difference between Seventh and Ninth Circuit pleading standards).

in a position to know the information stated. Lead Plaintiff meets the Ninth Circuit's standards. *See Daou*, 411 F.3d at 1015.

Defendants also argue the confidential witnesses cannot be relied upon because they did not work in Connetics' finance or accounting departments. Mot. at 33, 34 n.27. In the Ninth Circuit, however, a complaint need only "support the probability that a person in the position occupied by the source would possess the information alleged." *Daou*, 411 F.3d at 1015. There is no requirement that the witness participate in any decision-making or financial reporting. To do so would, in many cases, eliminate all potential witnesses except those who themselves perpetuated the fraud (most often, the defendants).[16]

B. The Complaint Raises A Strong Inference Of Scienter

A § 10(b) complaint must allege facts giving rise to a strong inference that the defendants acted with the required state of mind. 15 U.S.C. § 78u-4(b)(2). The required state of mind is satisfied where, as here, the complaint alleges defendants acted either knowingly or with deliberate recklessness. *See Nursing Home Pension Fund, Local 144 v. Oracle Corp.*, 380 F.3d 1226, 1230 (9th Cir. 2004). In *Tellabs*, the Supreme Court defined the "strong inference" standard as follows: "When the allegations are accepted as true and taken collectively, would a reasonable person deem the inference of scienter at least as strong as any opposing inference?"

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[16] *See CV Therapeutics*, 2004 WL 1753251, at *10; *cf. SupportSoft*, 2005 WL 3113082 (upholding complaint based largely on confidential sources). Defendants' reliance upon *In re U.S. Aggregates, Inc. Sec. Litig.*, 235 F. Supp. 2d 1063, 1075 (N.D. Cal. 2002), is also unavailing. Mot. at 33-34. There, the confidential witnesses had no contact with the defendants and merely relied on office rumor as the basis of their purported accounts. *Id.* Likewise inapposite are defendants' remaining authorities in which the court found confidential testimony not sufficiently particularized. Defendants' authorities stand for the unremarkable proposition that witnesses must be knowledgeable about the facts attributed to them and the complaint must plead facts establishing this reliability. *See, e.g., Cal. Pub. Employees' Ret. Sys. v. Chubb Corp.*, 394 F.3d 126, 149, 150-151 (3d Cir. 2004) ("All except one of these sources were employed in branch offices. . . . It is not apparent [how they] would possess information [about the] national level." "[Plaintiff] fails to explain how local employees who specialize in lines other than standard commercial would have obtained specific nationwide statistics regarding the standard commercial business); *Garfield v. NDC Health Corp.*, 466 F.3d 1255, 1265 (11th Cir. 2006) (plaintiff "failed to allege what was actually discussed at the meeting"). Here, the Complaint establishes the confidential witnesses had personal knowledge of the facts pleaded and are reliable sources upon which the Court may find particularity.

127 S. Ct. at 2511, 2513. "The inference that the defendant acted with scienter ***need not be irrefutable, i.e., of the 'smoking gun' genre, or even the 'most plausible of competing inferences.'"*** *Id*. at 2510. "***[T]he court's job is not to scrutinize each allegation in isolation but to assess all the allegations holistically***." *Id.* at 2511.[17]

1. Defendants' Actual Knowledge And Direct Participation Supports A Strong Inference Of Scienter

The Complaint details defendants' ***actual knowledge*** that Velac had failed an important pre-clinical safety test and stood little chance of being approved by the FDA, and defendants' ***direct participation*** in overstuffing the sales channels and understating the Company's reserves thereby overstating the Company's sales and revenue. For example, the Complaint details how defendants:

- Had ***actual knowledge of the results of the FDA-required study*** revealing that 89 out of 160 mice treated with Velac had developed cancer (¶¶52-56);
- ***Were informed by their own toxicology experts that the panel did not know of any drug that exhibited a "positive" dermal similar to Velac that ever had been approved by the FDA*** (¶¶57, 147);
- Had ***actual knowledge*** that the FDA had informed Connetics that the "positive dermal" experienced in the Mouse Study was ***a serious impediment for approval of Velac*** (¶¶68-71, 147-149);
- ***Directly ordered that unnecessary inventory be shipped***, particularly in the last two weeks of each quarter, so that Connetics could overstate its sales and revenue (¶¶112, 115(ii), 116-119);
- ***Directly instructed*** employees to contact distributors at quarter-end ***to pressure them to take more product than the Company knew was justified*** (¶115(i)); and
- ***Directly ordered manipulation of Connetics' forecasting process*** in attempts to "justify" selling more product to the distribution channel (¶¶113-114(i)-(iv)).

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[17] *In re Converium Holding AG Sec. Litig*., 04 Civ. 7897 (DLC), Slip. Op. (S.D.N.Y. Sept. 14, 2007) (refusing to weigh evidence after *Tellabs*; finding scienter adequately pleaded as to understated loss reserves). *Gompper v. VISX Inc.*, 298 F.3d 893, 897 (9th Cir. 2002), cited by defendants (Mot. at 12, 29) is superseded by *Tellabs*. Overruling *Gompper* in part, *Tellabs* held that the inference that the defendant acted with scienter need not be the "most plausible of competing inferences," only that a complaint must plead facts rendering an inference of scienter *at least as likely as* any plausible opposing inference. *Tellabs*, 127 S. Ct. at 2510-2513.

Defendants' actual knowledge that Velac was unsafe and FDA approval was unlikely is sufficient to plead scienter. This Court found a strong inference of scienter under similar circumstances in *CV Therapeutics*. There, like here, the complaint alleged that defendants had misled analysts and the investing public into believing that their novel drug was safe and effective for public use and was well on its way to FDA approval. Like here, defendants had actual knowledge – based on the results of clinical studies and communications with the FDA – that there were serious concerns regarding the drug's safety and efficacy and likelihood of FDA approval. 2004 WL 1753251, at *1-2. In *CV Therapeutics*, the Court found that scienter was sufficiently pled. *Id.* at *10; *see also No. 84 Employer-Teamster Joint Council Pension Trust Fund v. America West Holding Corp.*, 320 F.3d 920 (9th Cir. 2003) (scienter adequately pleaded where defendants failed to disclose FAA notice of maintenance problems).

Defendants claim the scienter allegations do not make logical sense because the Complaint alleges Connetics knew Velac would not be approved but nonetheless "proceeded to move ahead full speed . . . spending millions of dollars." Mot. at 2, 19. In rejecting a similar argument, the *Amylin* court explained:

> Amylin clearly *hoped* that its Phase III trials were sufficient to obtain FDA approval and undoubtedly spent significant amounts of money pursuing the trials to that end. However, Amylin's decision to forge ahead with the Phase III trials does not negate the reasonable inference that Amylin knew that the FDA had serious concerns about its study designs which could prevent the approval of Symlin.
>
> Based on the facts alleged by Plaintiffs, the most plausible inference to be drawn is that Amylin knew that there may be a problem with the methodology used in conjunction with the Phase III trials but took the calculated risk of continuing the trials and application process as originally planned. There is nothing unlawful about taking a calculated risk. However, if, as Plaintiffs allege, Defendants misled Plaintiffs about such risk by making assurances regarding the completeness of the data and the likelihood of FDA approval, Defendants may be held liable.[18]

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[18] *Amylin*, 2003 WL 21500525, at *5 (emphasis in original). Another similar case was recently decided in *NPS Pharms.*, 2007 WL 1976589, at *3. There, the court rejected defendants' argument that their "statements about the risks" of the drug "simply reveal a difference of opinion regarding data interpretation." *Id.* at *3. The Court explained, "[b]ut even if the [defendants'] claim is true, at the motion to dismiss stage, the court takes the plaintiff's well-pleaded factual allegations as accurate and does not weigh evidence." *Id.* The court, citing *Tellabs*, found that scienter was sufficiently pleaded where the complaint alleged, among other

The Complaint alleges further direct evidence of scienter – defendants' direct participation in channel stuffing and manipulating reserves to overstate sales and revenues. Eight confidential witnesses confirmed that, although knowing that the channel was already overstuffed, defendants Wiggans, Higgins and Vontz directed that even more product be put into the channel, particularly in the last two weeks of each quarter, in order to make Wall Street's numbers for sales and revenue. ¶¶112, 115(ii), 116-119. These same defendants also manipulated Connetics' forecasting process in attempts to justify "selling" more product into the distribution channel than was needed. ¶¶113-114(i)-(iv), 116-119. Vontz also instructed employees to contact distributors at the end of certain quarters and pressure them to take more product than the Company knew was justified. ¶115(i).

Similar allegations were upheld on remand in *Dura Pharm., Inc. v. Broudo*, 452 F. Supp. 2d 1005 (S.D. Cal. 2006). There, like here, the complaint relied on confidential witnesses who detailed how defendants falsely inflated the company's revenues and sales at the end of quarters by intentionally shipping excessive amounts of Ceclor CD and other products to wholesalers which were subject to price discounts, extended payment terms, and/or other incentives.[19]

The Complaint more than sufficiently pleads a strong inference of scienter, not only as to Connetics, but as to each individual defendant. By way of example only, Wiggans, Higgins and Vontz themselves selected the Mouse Study as the FDA-required study and then personally

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things, that defendants knew of the drug's risk yet concealed it, and concealed the likelihood of FDA approval. *Id.* at *5-6.

[19] *Id.* at 1026-30 (finding scienter adequately pleaded); *see also Stanley v. Safeskin Corp.*, 2000 U.S. Dist. LEXIS 14100, at *9-10 (S.D. Cal. Sept. 15, 2000) (strong inference of scienter found from detailed "allegations that incentives were granted to distributors and end users" "to purchase product they would not have otherwise needed"); *In re Lucent Tech., Inc. Sec. Litig.*, 217 F. Supp. 2d 529, 553 (D.N.J. 2002) (same); *In re Sci. Atlanta, Inc.*, 2002 U.S. Dist. LEXIS 25414, at *6, 25 (N.D. Ga. Dec. 23, 2002). Contrary to defendants' insinuation (Mot. at 32), channel stuffing is not limited to short periods. As an initial matter, defendants have admitted that Connetics' reserves were overstated for the entire Class Period, an overstatement that was caused by defendants' channel stuffing. In addition, courts have upheld complaints alleging longer periods of channel stuffing. *See, e.g., Dutton v. D&K Healthcare Res.*, 2006 U.S. Dist. LEXIS 42553, at *4-6, 68-90 (D. Mo. 2006) (upholding complaint against company alleging "defendants participated in 'channel-stuffing' transactions" of pharmaceuticals resulting in a restatement of financial results for "1999, 2000, 2001, and the first two quarters of 2002").

monitored the Mouse Study (¶¶52-56); Yaroshinsky and Krochmal (who were directly in charge of the pre-clinical testing) personally participated in the call with the FDA wherein the FDA informed them that the Mouse Study results were a serious impediment for FDA approval, and the substance of the call was immediately relayed to Wiggans, Higgins and Vontz (¶¶68-71); Wiggans, Higgins and Vontz directly ordered the channel stuffing and manipulation of forecasting process (¶¶112-115); and the individual defendants participated in suspicious insider trading (*see infra* Section IV.B.4) and/or had other motives to commit fraud (¶¶156-177).[20]

Defendants attempt to isolate (or ignore) each scienter allegation, wrench the allegations from context and then challenge each individual fact, standing alone. For example, defendants attempt to separate the channel stuffing allegations from the understated reserves, and then argue that the reserve allegations are based solely on "math." Mot. at 27-31. As explained in the Complaint, however, the channel stuffing and reserve issues are inter-related. *See* ¶¶101-108, 117, 119, 121, 124, 126, 143, 145. Indeed, Connetics has admitted that its document production in response to the SEC investigation into its channel-stuffing "included information on inventory in the distribution channel which is used in the reserve estimation process." ¶126. The entire channel stuffing/reserve understating scheme is supported by confidential witnesses who themselves were told directly by defendants to stuff the channels. Defendants' effort to fraction the Complaint's allegations is improper and directly contravenes the mandate of *Tellabs* requiring scienter to be weighed collectively. *Tellabs*, 127 S. Ct. at 2511; *see also CV Therapeutics*, 2004 WL 1753251, at *10. Even if, as defendants argue, some allegations, viewed individually, were to be lacking, the requisite inquiry focuses on whether the allegations, viewed

[20] *In re Read-Rite Corp. Sec. Litig.*, 115 F. Supp. 2d 1181 (N.D. Cal. 2000), *aff'd*, 335 F.3d 843 (9th Cir. 2003), cited by defendants (Mot. at 28) is inapposite. There, the complaint relied on post-class-period admissions by defendants to establish a strong inference of scienter. The court, however, found that the post-class-period admissions were not inconsistent with defendants' class-period statements. 35 F.3d at 847-48. This is not the case here where the Complaint alleges specific facts detailing defendants' actual contemporaneous knowledge and their direct ordering of channel-stuffing and manipulation of the forecasting process. In addition, here, the Complaint does not rely on the defendants' positions and importance of Velac for scienter, rather, these facts constitute additional indicia of scienter. *See Amylin*, 2002 WL 31520051, at *8; *see also Read-Rite*, 335 F.3d at 848 (positions may establish a "reasonable inference" that defendants would be aware of falsity).

in their totality, raise a strong inference of scienter. *See Daou Sys.*, 411 F.3d at 1024 (scienter sufficiently pleaded in the totality, despite that individual allegations would be insufficient alone; reversing dismissal of complaint); *America West*, 320 F.3d at 945 (same).[21]

2. Defendants Repeatedly Assured Investors They Were Focused On And Monitoring Velac As It Was Critical To The Company's Future

Velac was the key revenue driver in the Company's plans for future growth. ¶2 ("our biggest selling product"). Velac's importance to Connetics supports the strong inference that defendants were, in fact, knowledgeable about important Velac test results such as the Mouse Study. *See Amylin*, 2002 WL 31520051, at *8 (scienter sufficiently pleaded as to individual defendants where drug was the company's "primary drug candidate"); *In re Viropharma, Inc. Sec. Litig.*, 2003 WL 1824914, at *9 (E.D. Pa. Apr. 7, 2003) (where fraud involves pharmaceutical company's "leading product and Defendants were the highest ranking members of the company, it can be assumed that the Defendants were aware of these facts"); *see also America West*, 320 F.3d at 943 n.21 (notion that a major company issue did not come to the attention of management was "patently incredible" and "absurd").

Indeed, the Insider Defendants repeatedly represented to the market that they were focused on the development of Velac and were keeping themselves personally apprised of the Velac regulatory and testing processes.[22] Thus, defendants' own representations support a strong inference they knew the results of the Mouse Study and the panel's conclusion that it knew of no drug with similar carcinogenic effects ever approved by the FDA. *See, e.g., Daou,*

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[21] Unlike the channel stuffing cases relied upon by defendants (Mot. at 30-31), here, defendants' channel stuffing was part of their overall scheme which understated reserves (due to, for example, the inevitable return of products) and overstated sales and revenue – the truth of which Connetics admits through its restatement. ¶¶120, 126, 130. Defendants' cases are inapposite, either containing generalized conclusory allegations, little indicia of scienter, and/or no restatement. *See, e.g., In re Ashworth, Inc. Sec. Litig.*, 2000 WL 33176041 (S.D. Cal. July 18, 2000) (dismissing generalized channel stuffing claims where there was no restatement to establish falsity).

[22] *See, e.g.*, ¶¶151-152, 41-43, 48-49, 51, 59-60, 78-79, 124, 180, 186-190, 192-193, 199, 202, 205-206, 208, 210-211, 219, 221-225, 227-228, 239, 241-246, 248-249, 259, 261-262, 264, 266-267, 277, 280, 282-285, 287-288, 296, 298-299, 305-307, 309, 313, 315-316, 324, 326-331.

411 F.3d at 1022 (admissions from top executives that they are monitoring relevant processes weigh in favor of inferring scienter); *Nursing Home Pension Fund*, 380 F.3d at 1234-35 (same).

3. Defendants' Admitted GAAP Violations And Inadequate Internal Controls Further Support Scienter

Defendants' GAAP violations provide additional evidence of scienter, especially when, as here, they are coupled with other circumstances indicative of fraudulent intent. *See Daou*, 411 F.3d at 1022 (significant GAAP violations can provide evidence of scienter so long as they are pled with particularity). "After all, books do not cook themselves." *In re McKesson HBOC, Inc. Sec. Litig.*, 126 F. Supp. 2d 1248, 1273 (N.D. Cal. 2000).

Defendants intentionally stuffed the distribution channels to artificially inflate Connetics' sales and revenue. Moreover, because sales of the Company's products were subject to a right of return or potential rebates, substantial portions of the shipments did not qualify as "sales" at all, and reporting them as such rendered the Company's financial statements materially false and misleading in violation of GAAP. ¶¶10, 138-145. The Company has admitted it materially understated its accruals for product rebates, chargebacks, and the amount of future product returns due to "errors in the accounting" for these items. ¶130. In other words, the Company admitted that it had enough information on hand ***at the time it filed its financial statements*** to prepare them in accordance with GAAP, but it ignored the available information. ¶131.

The Company has also now admitted that there were undisclosed material weaknesses in its internal controls over financial reporting. "Material weakness" is defined as "a significant deficiency or a combination of significant deficiencies which results *in more than a remote likelihood that material misstatement of our annual or interim financial statements would not be prevented* . . . ." ¶132. These admissions directly contradict the Sarbanes-Oxley certifications that defendants Wiggans and Higgins signed, in which they personally vouched for the adequacy of Connetics' internal and disclosure controls. ¶¶19, 21, 192-194, 210-212, 227-229, 248-250, 266-268, 287-289, 298-300, 315-318. Courts within this Circuit have held that these certifications that are later admitted to be false support an inference of scienter "because they provide evidence either that defendants knew about the improper [accounting] . . . or,

alternatively, knew that the [internal] controls they attested to were inadequate." *Lattice Semiconductor*, 2006 WL 538756, at *18. Defendants' false certifications, in addition to their signing of the SEC filings themselves that contained the false financial statements, further support an inference that they knew the statements were false when made.

4. Defendants' Unusual And Suspicious Insider Trading And Other Motives Further Support A Strong Inference Of Scienter

"[Insider] trading in unusual or 'suspicious amounts or at suspicious times is probative of' scienter." *In re HI/fn, Inc. Sec. Litig.*, 2000 WL 33775286, at *10 (N.D. Cal. Aug. 9, 2000). Although the Complaint does not rely upon insider trading allegations alone, defendants improperly attempt to isolate the insider selling allegations, claiming that, by themselves, they are insufficient to establish scienter. *See, e.g.*, Mot. at 23-25. "By analyzing the insider selling allegations in isolation, defendants ignore the fact that plaintiffs do not seek to sustain scienter on insider trading alone but as one component 'in combination' with the other factors discussed." *In re Terayon Commc'ns Sys., Inc. Sec. Litig.*, 2002 WL 989480, at *12 (N.D. Cal. Mar. 29, 2002).

"Relevant factors in determining whether sales are suspicious include (1) the amount and percentage of shares sold, (2) the timing of the sales, and (3) whether the sales were consistent with a past pattern of trading or other circumstances." *HI/fn*, 2000 WL 33775286, at *10. A strong inference of scienter may be inferred where defendants' "sales were made near the time [when] misrepresentations about [the Company's] financial future were made to the market." *Id.* at *31. Conspicuously timed sales "near the stock's peak" "calculated to maximize the personal benefit from undisclosed inside information" are also probative of a strong inference of scienter. *See, e.g.*, *America West*, 320 F.3d at 939-40. Here, defendants' insider sales are suspicious in numerous respects.

Defendants Yaroshinsky and Zak pocketed $1.58 million by taking bearish positions in Connetics stock based on Yaroshinsky's inside information that the FDA would not approve Velac. ¶¶86-95. *See also* Lead Plaintiff's accompanying Opposition to Yaroshinsky Motion to Dismiss. The most reasonable inference that can be drawn from their massive selling is that

Yaroshinsky knew defendants' false statements were misleading investors and that the Company's stock price was inflated. ¶¶86-95. Yaroshinsky's scienter is attributable to Connetics. *See CV Therapeutics*, 2004 WL 1753251, at *10.

Defendants Wiggans, Higgins and Vontz's sales of Connetics stock also support a strong inference of scienter. Their sales of over $9 million during the Class Period far exceeded their sales in the two years prior. ¶¶165-166. Moreover, the vast majority of defendants' insider sales were at prices near or above $20, far above the stock price of $7.76 after partial disclosures of defendants' fraud. *See* ¶¶165, 333. And, defendants sold at opportune times – including, for example, a stock sale two days after the Company convened a panel of experts to assess the Mouse Study results and a sale the day before the Company's partial disclosure of its conference call with the FDA. *See* ¶¶57, 74-77, 165.

Defendants argue "plaintiff's claim of 'actual knowledge' is irreconcilable with the concrete business decisions Connetics made following the preclinical study" and that "the business decisions Connetics made would simply make no sense if defendants 'knew' all along that Velac would not be approved." Mot. at 19; *see also id.* at 2. Defendants' argument fails in several regards, and notably fails to take into consideration the Insider Defendants' motives to cause Connetics to spend millions of dollars to maintain the false illusion that Velac would be approved by the FDA – while the Insider Defendants sold millions of dollars of Connetics stock at artificially inflated prices for their own personal gain.

Defendants further contend that each of the Insider Defendants sold only a small portion of their total holdings in Connetics, which defendants assert "refute[s] any inference of scienter." Mot. at 23-24. In the Ninth Circuit, insider selling in small amounts, or an absence of insider sales by one or more defendants, does not "refute" a strong inference of scienter. *See America West*, 320 F.3d at 944 Moreover, defendants' entire argument relies upon their Exhibit 39 – which inaccurately inflates the Insider Defendants' retained stock holdings and distorts downwards the percentage of their portfolios they sold by including worthless options in the

calculation – and should therefore be stricken.[23] The Court should not consider the Insider Defendants' worthless, underwater options in calculating the amount of the retained shares. *Cf. America West*, 320 F.3d at 939 n.16 (in calculating the percentage of defendants' sales, the court's analysis stated the "percentage is derived from the common stock and exercised options" but did not include unexercised options).

Defendants further contend their sales were made pursuant to Rule 10b5-1 trading plans and therefore are "not suspicious." Mot. at 25, n.20. Defendants, however, have not disclosed the terms of their purported trading plans. Moreover, Wiggans, Higgins and Vontz entered into Rule 10b5-1 trading plans ***during*** the Class Period on four, three and two separate occasions, respectively, while in possession of material, undisclosed information. *See* Ex. A to the Declaration of David R. Stickney ("Ex. A") submitted herewith. Defendants' "attempt to use the 10b5-1 Plan[s] as a non-suspicious explanation is flawed because, *inter alia*, [defendants] entered into the Plan[s] during the Class Period." *Cent. Laborers' Pension Fund v. Integrated Elec. Servs.*, 2007 WL 2367776, at *6 (5th Cir. Aug. 21, 2007) (rejecting defendant's argument and finding insider sales contributed to strong inference of scienter). A trading plan is only valid if entered into "***[b]efore*** becoming aware of the information."[24] Defendants' use of Rule 10b5-1 trading plans is highly suspicious and further supports a strong inference of scienter.

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[23] *See* Lead Plaintiff's accompanying Opposition to Judicial Notice. Exhibit 39 purports to set forth each of the Insider Defendants' stock sales as a percentage of their individual total holdings remaining "as of May 23, 2006, as reported in Connetics' 2006 proxy statement." Ex. 39 at n.1. In calculating the percentage of their total holdings sold during the Class Period, defendants improperly inflated their total holdings by including valueless stock options, *i.e.*, underwater options. For example, in Exhibit 39 defendants assert Krochmal owned 214,193 shares as of May 23, 2006, which is the number found in the Company's 2006 proxy statement. The 2006 proxy also states: "Dr. Krochmal's total includes options to purchase 153,333 shares of common stock that will be exercisable on or before May 23, 2006." Ex. 27 at 10. Importantly, the 2006 proxy statement notes that all of Krochmal's options were worthless as of December 31, 2005 (and therefore worthless on May 23, 2006 when the Company's stock price was lower than it was on December 31, 2005). Ex. 27 at 24. Defendants have not disclosed, either publicly or before the Court, the amount of defendants' unexercised options that were underwater (and therefore worthless) that they have included as part of their personal, retained holdings in Exhibit 39.

[24] 17 C.F.R. § 240.10b5-1(c)(A)(1). Here, for example, Wiggans entered into a trading plan on March 14, 2005 – after the Company learned the results of the Mouse Study but one month

In addition to insider trading, the Complaint alleges at least three additional motives for the fraud: (1) to effectuate a private bond offering so that defendants could use the Company's proceeds to repurchase shares, thereby inflating the market price of the individual defendants' personal shares (¶¶156-159, 177); (2) to reap substantial compensation through their salaries, bonuses, and stock options which were dependent on achieving certain "performance" goals (¶¶168-172, 175-176); and (3) to allow the Company to meet or exceed analysts expectations (¶¶160-164, 173-174). These allegations further support a strong inference of scienter. *Livid Holdings Ltd v. Salomon Smith Barney, Inc.*, 416 F.3d 940, 949 (9th Cir. 2005) (motive and opportunity to commit securities fraud, coupled with other allegations of wrongdoing, are sufficient to raise a strong inference of scienter).[25]

C. Defendants' Statements Are Not Protected By The PSLRA Safe Harbor

Defendants do not – and cannot – argue that the PSLRA safe harbor protects them from liability for issuing the Company's false financial statements. *See* 15 U.S.C. § 78u-5(b)(2)(A). The PSLRA's safe harbor applies only to forward-looking statements, and only to the extent that such statements are actually identified as such and accompanied by meaningful cautionary language identifying important factors that could cause actual results to materially differ. 15 U.S.C. § 78u-5(c). Even if a statement is forward-looking, identified as such, and accompanied

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before the Company's conference call with the FDA. *See* Ex. A and ¶¶56, 69, 74-77. On the very same day Wiggans entered into the March 14, 10b5-1 trading plan, he sold 30,000 shares at $27.71 pursuant to a Rule 10b5-1 plan Ex. 24. This was Wiggans' largest stock sale for any given day (or month for that matter) during the Class Period and at least as far back as July 1, 2001. *See* ¶¶165-166; Ex. 24. Moreover, this sale was curiously fortuitous for Wiggans in that it was very close to the Company's Class Period high of $29. *See* ¶165; Ex. 40. Similarly, Higgins entered into trading plans twice *after* learning the results of the Mouse Study. *See* Ex. A and ¶56. Suspiciously, Higgins sold over $2.5 million in Connetics shares between June 15, 2004 and June 10, 2005 – the peak of Connetics' stock price and the period between Connetics obtaining the results of the Mouse Study and the Company's disclosure of the FDA non-approval. *See* ¶¶56-57, 81-83, 165. Nearly 75% of Higgins' $3.4 million in trading during the 2.5 year-long Class Period was when Connetics stock price was artificially inflated by defendants' false statements concerning Velac.

[25] Defendants again attempt to parse out certain indicia of scienter and ask the Court to ignore them. Mot. at 25-26. These additional motive allegations are not alleged in isolation, but rather provide additional indicia of scienter. In addition, unlike cases relied upon by defendants (Mot. at 25-26), here the Complaint provides specific, non-general motive allegations.

by meaningful cautionary language, the Ninth Circuit holds that "a person may be held liable if the 'forward-looking statement' is made with 'actual knowledge . . . that the statement was false or misleading.'"[26] A forward-looking statement may be actionable "if any of the following three factors are accurate: (1) the statement is not genuinely believed; (2) there lacks a reasonable foundation for the belief; or (3) the speaker is aware of undisclosed facts that tend to discredit the accuracy of the projection." *InterMune*, 2004 WL 1737264, at *4.

Here, defendants' safe harbor argument fails for several reasons. First, as explained above, *see supra* Section IV.B.1, the Complaint establishes a strong inference that the defendants knew their statements were misleading when made. When, as here, a complaint adequately alleges a strong inference that statements or omissions were made with actual knowledge of facts rendering the statements misleading, the safe harbor provision does not apply. *See Terayon*, 2002 WL 989480, at *3 (purportedly forward looking statement actionable where "at the time the defendants made optimistic statements they already had knowledge of contradictory facts and information that they did not disclose to investors"); *cf. InterMune*, 2004 WL 1737264, at *5 ("To the extent that a statement is forward-looking and is not based on the most accurate information available to defendants, it would not be protected by the general safe harbor provision.").

Second, defendants' false statements were not forward-looking. Defendants' incorrectly conclude that "plaintiff is necessarily challenging forward-looking statements" protected by the PSLRA safe harbor provision because "the gravaman of plaintiff's claims is that Connetics allegedly misrepresented the likelihood that Velac would be approved by the FDA." Mot. at 13; *see also id.* at 15, 16. To be clear, the Complaint does not premise liability upon defendants' inability to predict future events. Rather, the Complaint alleges defendants' concealment of

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[26] *America West*, 320 F.3d at 936. Defendants' reliance on *Harris v. Ivax Corp.*, 182 F.3d 799, 803-04 (11th Cir. 1999) for the proposition that a statement is protected by the safe harbor regardless of whether a defendant knows it to be false, *see* Mot. at 16, is contrary to the law in this circuit. *See, e.g., In re Elec. Arts Inc. Sec. Litig.*, 2006 WL 27201, at *1 (N.D. Cal. Jan. 5, 2006) ("forward-looking statements accompanied by cautionary statements . . . are actionable if knowingly false when made").

then-existing facts – that the Mouse Study ***indicated*** that Velac caused cancer at alarming rates (¶¶52-57); that defendants ***had been informed*** by their own experts that they did not know of any drug that exhibited a "positive" dermal similar to Velac that ever had been approved by the FDA (¶¶57, 147); and (later) that the FDA ***had expressly informed*** Connetics that the "positive dermal" experienced in the Mouse Study was a serious impediment for approval of Velac (¶¶68-71, 147-149). Defendants concealed these facts while at the same time making misleading statements concerning Velac's safety and efficacy. Regardless of defendants' assertions, these statements concealed historic facts about Velac. *See America West,* 320 F.3d at 936-37 (statement concerning impact of federal agency's ruling on company "going forward" not forward looking and not protected by safe harbor because "any corporation could shield itself from future exposure for past misconduct" by simply changing tense of disclosure).

This Court's holding in *CV Therapeutics*, 2004 WL 1753251, is instructive. There, this Court rejected defendants' PSLRA safe harbor argument, holding "when the defendants possessed and failed to disclose detailed information about the FDA's serious reservations concerning Raxena's safety and efficacy, they failed to disclose ***historical*** facts." *Id.* at *10. The same logic applies here with regard to the defendants' failure to disclose the results of the Tg.AC study and the expert panel's conclusions regarding the study.

Even if defendants' statements were forward-looking, their safe harbor argument separately fails because Connetics' purported risk disclosures were not "meaningful." Defendants can only cite to vague, boilerplate warnings that could apply to any pharmaceutical company. Mot. at 15 (the FDA "may not interpret our clinical data the way we do"). This Court rejected nearly identical boilerplate risk disclosure where, as here, the defendants had material information indicating FDA approval was unlikely. *See CV Therapeutics,* 2004 WL 1753251, at *11 ("use of the word 'may' was misleading" where company stated "the FDA may interpret these data differently"); *see also Amylin,* 2003 WL 21500525, at *7 ("Vague or boilerplate disclaimers are insufficient to invoke safe harbor protection.") In *Immune Response,* 375 F. Supp. 2d at 1002, the defendant company emphasized positive aspects of a study of a drug for which it was seeking FDA approval, but did not reveal study findings likely to complicate efforts

to obtain that approval. *Id.* at 1034-35. A company press release had warned that "future studies may never be completed or . . . prolonged delays may occur," but the court found that, in light of the press release's optimistic tone, these warnings were not meaningful under the PSLRA's safe harbor. *Id*.

Defendants' reliance upon *In re Syntex Corp. Sec. Litig*., 95 F.3d 922 (9th Cir. 1996), is unfounded. Mot. at 17. As explained by the court in *Terayon* when distinguishing *Syntex,* "[t]he *Syntex* court ruled that defendants' statements about the likelihood of FDA approval were merely a 'prediction far in advance' and were not actionable since plaintiffs had presented no evidence that the statement was false and misleading when made." 2002 WL 989480, at *3. In *Syntex*, the statements at issue were not misleading because the defendants did not omit to disclose material facts known to them at the same time they were communicating with the market about the likelihood of FDA approval. *See Syntex*, 95 F.3d at 930 ("Nothing in this case indicates that the company had knowledge contradicting its ability to achieve FDA approval . . . ."). "Defendants here cannot legitimately claim they had no knowledge contradictory to their statements." *Terayon*, 2002 WL 989480, at *3. Defendants knew the Tg.AC study results strongly indicated that Velac caused cancer and had knowledge contradicting their favorable statements asserting FDA approval was going to happen. ¶¶56-57, 68-70. *Syntex* is further distinguishable because, unlike here, the "FDA did actually issue its approval" for the drug.[27]

D. The Complaint Alleges Loss Causation

Loss causation requires that a complaint allege that the "defendant's misrepresentation . . . proximately caused the plaintiff's economic loss." *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 346 (2005). *Dura* holds that at the pleading stage a complaint need only provide a defendant

[27] *Syntex*, 95 F.3d at 930. Accordingly, defendants err in suggesting the purportedly omitted information regarding faulty testing procedures in *Syntex* is comparable to defendants' omissions here. Mot. at 17-18. The problems in *Syntex* were able to be fixed whereas the fact Velac caused cancer could not be altered. Defendants' reliance on *Noble* is similarly unavailing. Mot. at 15 (citing 2005 WL 4161977, at *2). There, plaintiffs alleged merely that defendants made positive statements about the outcomes of clinical trials but failed to disclose that testing protocol rendered the data inconclusive – information that was already within the public domain. Further, *Noble* relies upon *MedImmune* and is equally flawed, as explained *supra* note 12.

with some indication of the loss and the causal connection that the plaintiff has in mind. *Id.* at 347. The loss causation requirement is "not meant to impose a great burden upon a plaintiff" and, in accordance with Federal Rule of Civil Procedure 8(a)(2), requires only a short and plain statement giving "notice of what the relevant economic loss might be or of what the causal connection might be between the loss and the misrepresentation." *Id.*

Here, the Complaint details how, when the truth about the Company was revealed to the market through a series of partial disclosures, the inflation that had been caused by defendants' misrepresentations and omissions was eliminated from the stock price and investors, including Lead Plaintiff, suffered losses. *See, e.g.*, ¶¶333, 334; *see also* ¶¶72-79, 83-85, 96-98, 121, 123-125, 127-129.

Defendants concede that previously undisclosed information was revealed to the market on April 26, 2005 (Mot. at 8-9; Yaroshinsky Mot. at 10; *see* ¶¶57, 72-79, 333(i)) and on June 13, 2005 (Mot. at 1; *see* ¶¶83-85, 333(ii)). They instead argue that the April 26th revelation did not disclose that defendants had been committing "fraud." (Mot. at 26, arguing that loss causation is not satisfied because the April 26 disclosure purportedly "*did not 'reveal' any putative fraud*; rather, among other things, it merely summarized recent communications with the FDA"). Neither the *Dura* Court, the Ninth Circuit, nor any other court, has taken the position advocated by defendants – that there needs to be an admission by the company that it committed "fraud." Indeed, the Ninth Circuit rejected this argument in *Daou*. There, the district court had dismissed the complaint for failure to adequately plead loss causation, explaining that "the [Third Amended Complaint] does not allege that there were any negative public statements, announcements or disclosures at the time the stock price dropped that Defendants were engaged in improper accounting practices." 411 F.3d at 1026. The Ninth Circuit reversed, finding it sufficient that the price of Daou's stock fell after defendants began to reveal figures "showing the company's true financial condition." *Id.* at 1026. Under *Dura* and *Daou*, an admission of "fraud" is not required.

Defendants also do not – and cannot – dispute that previously undisclosed information was revealed on May 3, 2006, when Connetics announced that it would be restating its 2005

financial statements. ¶¶121, 123-124, 333(ii). Defendants argue there is no loss causation because on May 4, 2006, the closing price of the stock was up slightly from the closing price on May 3, 2006. Mot. at 36. Defendants' own stock chart (Ex. 41) reveals that, although the official press release was issued after the close of the market on May 3, 2006, there was leakage into the market during the trading day on May 3, 2006. This is apparent from the ***over 700% increase in trading volume*** from May 2, 2006 (242,800) to May 3, 2006 (1,780,300), and the stock declining from a close on May 2, 2006 of $15.27, to a close on May 3, 2006 of $13.76. In any event, the exact timing of when the new information influenced the stock price is an area for expert testimony, but it is clear that defendants' disclosure of the restatement caused plaintiffs to suffer losses.

Despite the fact that following the July 10, 2006 announcement, Connetics' stock price dropped by nearly $4.00, (or 34%), defendants claim that the Complaint fails to cite any previously undisclosed information in that announcement. Mot. at 37. The Complaint explains, however, how Connetics disclosed for the first time on June 10, 2006 that the guidance just recently provided on May 3, 2006 was wrong, due in part "to the Company's decision to reduce wholesaler inventory by shipping product volumes that were below estimated prescription demand . . . ." ¶127; *see also* ¶¶124, 127-129, 333(iv).

Defendants' argument that the Complaint cannot plead loss causation based on the July 10, 2006 disclosure because it occurred one day after the end of the Class Period is likewise unsupported, and makes no sense. Mot. at 36. A "class period" defines the class of plaintiffs who bring the lawsuit, *i.e.*, investors who purchased shares at inflated prices and then were damaged when the true facts become known and the stock price declined. Once the "truth" became fully revealed on July 10, 2006, no investor purchasing on or after that date would have a viable claim for fraud in this case, and thus such investors are not included as "class members." Rather, because the truth was revealed on July 10, 2006, the class period ends on July 9, 2006, the last trading day *before* the full truth was revealed. Indeed, the court on remand from the

Supreme Court's *Dura* decision rejected a similar defense argument, finding that a corrective disclosure may occur even over nine months after the class period ends.[28]

And finally, defendants argue that there is no loss causation pleaded as to a claim based on defendants' "channel stuffing," because "plaintiff can point to no disclosure, either by Connetics or a third party, suggesting that Connetics had sold unwanted product to its customers in 2004 and 2005." Mot. at 37. Again, defendants fail to apply Ninth Circuit law on loss causation. As explained in *Daou,* all that is required is that the Complaint provide defendants with "some indication that the drop in [Connetics'] stock price was causally related" to defendants' false statements or omissions. *Daou,* 411 F.3d at 1026. The Complaint explains that defendants' channel-stuffing caused the Company's reserves to be materially understated and its revenue and sales to be overstated – truths that were all revealed through the May 3, 2006 and July 10, 2006 announcements.[29]

E. Defendants' Purported "Standing" Argument Is A Red Herring

Conflating "standing" with loss causation, defendants attempt to avoid liability by contending that Lead Plaintiff did not own stock on one day in the middle of the Class Period, June 13, 2005, the date that the second partial disclosure was made. Mot. at 13.

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[28] *Dura*, 452 F. Supp. 2d at 1023; *cf. Zelman v. JDS Uniphase Corp.*, 376 F. Supp. 2d 956, 966 (N.D. Cal. 2005). Defendants' reliance on *Powell v. Idacorp., Inc.*, 2007 WL 1498881, at *14 (D. Idaho May 21, 2007), is misplaced. Mot. at 27 n.21, 36. Not only does the ruling (and purported reasoning, at *14) not make sense (as explained above), but it is expressly contrary to Ninth Circuit law. *See, e.g., id.* at *13-14 (distinguishing Ninth Circuit's *Daou* opinion and rejecting that partial disclosures can satisfy loss causation). An appeal of that decision is pending in the Ninth Circuit. *See* Appeal Docketed at No. 07-35515. Even if *Powell* remains good law, however, it is distinguishable. There, the complaint alleged only partial disclosures and defendants argued that the truth was not revealed "until well after the Class Period had ended." *Id.* at *13. In contrast, here, the Class Period ends the day before the full disclosure was made.

[29] *See* ¶¶101-108, 117, 119, 121, 124, 126, 143, 145; *see also Daou*, 411 F.3d at 1026. Defendants' authorities are inapposite. For example, in the unpublished decision in *In re D.E. & J. Ltd. P'ship v. Conaway*, 133 Fed. Appx. 994, 1000 (6th Cir. 2005), plaintiff merely pleaded that "in reliance on the integrity of the market, they paid artificially inflated prices for Kmart publicly traded securities" and failed to "provide[] the defendants with notice of what the relevant economic loss might be or of what the causal connection might be between the loss and the misrepresentation." Here, plaintiff more than sufficiently explains how defendants' channel-stuffing resulted in overstated financial results that were subsequently revealed to be false, causing Connetics stock to drop.

Standing contains three elements: First, the plaintiff must have suffered an "injury in fact"; second, there must be a causal connection between the injury and the conduct complained of; and, third, it must be "likely," as opposed to merely "speculative," that the injury will be "redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). Here, Lead Plaintiff suffered an injury caused by defendants' misconduct when the price for stock that Lead Plaintiff had purchased at artificially inflated prices fell after the truth that defendants had previously concealed was disclosed, and this injury will be redressed by a favorable decision in this case. Defendants completely ignore that the June 13, 2005 release was but one of the many partial disclosures that revealed the truth. *See, e.g.*, ¶333. Because Lead Plaintiff held stock through the first partial disclosure and subsequent stock price drop, on April 26, 2005 (and through each of the other several partial disclosures and stock price drops, including, among others, in May 2006 and July 2006), Lead Plaintiff suffered an injury caused by defendants' misconduct that will be redressed in this case.

Defendants' argument has been rejected by other courts. For example, in *In re VeriSign, Inc. Sec. Litig.*, 2005 WL 88969 (N.D. Cal. Jan. 13, 2005), the court rejected defendants' argument that the lead plaintiffs lacked "standing" to base their claims upon any misrepresentations made after the date of their last stock purchase. *Id.* at *5. "'Once threshold individual standing by the class representative is met, a proper party to raise a particular issue is before the court, and there remains no further separate class standing requirement in the constitutional sense.' 'The presence of individual standing is sufficient to confer the right to assert issues that are common to the class . . . .'"[30]

[30] *Id.* at *4-5; *see also Alfus v. Pyramid Tech. Corp.*, 764 F. Supp. 598, 605-07 (N.D. Cal. 1991) (class representative has standing if he is injured by defendants' conduct and that injury is typical of all class members; the class period is not confined to the dates before the representatives' purchases because to so confine the class period would be arbitrary and would imply that only someone who bought on the last day of the class period could bring an action based on the dates alleged in the complaint); *In re WorldCom, Inc. Sec. Litig.*, 219 F.R.D. 267, 283 (S.D.N.Y. 2003) (plaintiffs had standing to pursue claims that "arise[] from the same course of conduct and the same Offerings, and involve[] the same defendants, legal theories and factual allegations," even though not all of the plaintiffs participated in the offerings).

The cases relied on by defendants are inapposite. First, the out-of-circuit case of *In re Compuware Sec. Litig.*, 386 F. Supp. 2d 913 (E.D. Mich. 2005), Mot. at 13, merely stands for the proposition that loss causation must be sufficiently pleaded under *Dura*. As explained above, Lead Plaintiff suffered damages when the truth was partially disclosed. Likewise, *Shurkin v. Golden State Vintners, Inc.*, 471 F. Supp. 2d 998 (N.D. Cal. 2006), does not support defendants' argument. *Shurkin* purports to rely upon *VeriSign* but misreads the case (which, as detailed above, supports plaintiffs' position here). Further, *Shurkin* is against the weight of authority and an appeal of *Shurkin* is currently pending. *See* Appeal Docket at No. 07-15762 (9th Cir.).

Ostensibly arguing plaintiff lacks standing, defendants assert: "Despite the so-called 'fraud' revealed on June 13, 2005, plaintiff decided to buy shares thereafter even though Connetics was run by precisely the same management team." Mot. at 3 and n.1. The June 13 partial disclosure removed artificial inflation from the stock price. ¶¶82-85. At the time, when the stock price was lower, Lead Plaintiff purchased without knowing the inside information about defendants' practices. Lead Plaintiff was unaware that the SEC would file a complaint disclosing aspects of defendants' Velac-related fraud, ¶¶96-98, and that Connetics' financial statements had been false and would be restated. ¶¶121-127.

V. THE COMPLAINT STATES A CLAIM FOR CONTROL PERSON LIABILITY

A complaint sufficiently states a claim under § 20(a) of the Exchange Act if it alleges (1) a primary violation of the federal securities law and (2) that the defendant exercised actual power or control over the primary violator. *See America West,* 320 F.3d at 945.

The Complaint satisfies the first prong by pleading a primary violation of federal securities law by defendant Connetics. As to the second prong – whether or not a person is a "control person" – this is "'an intensely factual question.'" *Id.* at 945. Here, the Complaint details how defendants Wiggans, Higgins and Vontz exercised actual power or control over Connetics. These defendants were not only the top officers of the Company – as CEO and President, COO and President, and Executive Vice President, Finance and Administration and Corporate Development, respectively – they were also members of Connetics' "Management Executive Committee." ¶¶147-154. These defendants also participated in numerous conference

calls with analysts and investors, and signed the Company's SEC filings that were publicly filed during the Class Period, as well as Sarbanes-Oxley certifications (Wiggans and Higgins only) admitting that they were responsible for "establishing and maintaining disclosure controls and procedures . . . and internal control over financial reporting." ¶193; *see also supra* note 22 and surrounding text. Vontz was also in charge of overseeing the pre-clinical testing of Velac and was involved in every step of the developmental process for the drug, including overseeing the Mouse Study. ¶147. These allegations readily satisfy the requirements for pleading control person liability. *See, e.g., CV Therapeutics*, 2004 WL 1753251, at *11-12 (finding control person sufficiently pleaded where complaint alleged defendants, CEO and CFO, were responsible for press releases and financial reporting, and signed SEC documents).

VI. THE COMPLAINT STATES A CLAIM FOR VIOLATIONS OF § 20A

Section 20A provides a cause of action to plaintiffs who purchased stock "contemporaneously" with a defendant who sold stock while in possession of material, non-public information. 15 U.S.C. § 78t(d). "Claims under Section 20A are derivative and therefore require an independent violation of the Exchange Act." *Johnson v. Aljian*, 490 F.3d 778, 781 (9th Cir. 2007). Defendants' primary contention is that "plaintiff has failed to plead an underlying violation of Section 10(b). . . ." Mot. at 38. As set forth above, the Complaint sufficiently pleads violations of § 10(b), and as such satisfies the underlying predicate violation.

Defendants further claim that the § 20A claims fail because the Complaint does not plead "particularized facts establishing that these defendants sold Connetics stock on the basis of material non-public information." Mot. at 38. "[A] purchase or sale of a security of an issuer is 'on the basis of' material, non-public information about that security or issuer if the person making the purchase or sale was aware of the material nonpublic information when the person made the purchase or sale." 17 C.F.R. § 240.10b5-1. Here, the Complaint adequately pleads that defendants were aware of material nonpublic information throughout the Class Period, including at the times defendants sold Connetics securities and at the times defendants entered into Rule 10b5-1 trading plans. *See supra* Section IV.B.

Finally, defendants Wiggans and Vontz argue that Lead Plaintiff does not have standing to bring § 20A claims against them because Lead Plaintiff did not purchase Connetics stock "contemporaneously" with a sale by either Wiggans or Vontz. Mot. at 38. Defendants admit, as they must, that Lead Plaintiff traded contemporaneously with Higgins.[31] Accordingly, Lead Plaintiff has standing to bring a § 20A claim. *See Hein v. Freedom from Religion Found., Inc.*, 127 S. Ct. 2553, 2562 (2007) ("The requisite elements of Article III standing are well established: A plaintiff must allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief."). Defendants' contention – that Lead Plaintiff needs to have standing to bring a § 20A claim in an individual capacity against every defendant in order to assert claims on behalf of the class of persons who purchased contemporaneously with defendants Wiggans and Vontz – is not required by Article III and would contravene Congressional intent in passing the PSLRA that sought to encourage institutional investors to serve as lead plaintiffs.[32] Accordingly, the Complaint establishes standing to bring the § 20A claims.

VII. CONCLUSION

For the foregoing reasons, defendants' motion to dismiss should be denied in its entirety. In the event the Court finds deficiencies in the Complaint, Lead Plaintiff respectfully requests leave to amend. In the Ninth Circuit, leave to amend is freely given unless the Complaint could not possibly be cured by the allegation of other facts. *See Lopez v. Smith*, 203 F.3d 1122, 1130

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[31] *Id.* "Under § 20A, any defendant who violated § 10(b) or related rules by purchasing or selling a security is liable to any person who traded securities 'contemporaneously' with the defendant. The precise scope of the term contemporaneously is not defined in § 20A [but] various courts have read this requirement to encompass trades on the same day, within the same week, within a month, and including 'the entire period while relevant and non-public information remained undisclosed.'" *In re Qwest Commc'ns Int'l Sec. Litig.*, 396 F. Supp. 2d 1178, 1201 (D. Colo. 2004).

[32] *See In re Cendant Corp. Litig.*, 60 F. Supp. 2d 354, 378-379 (D.N.J. 1999) (allegation that one class representative traded on at least one of the days that the defendant traded satisfied contemporaneous requirement). s*ee also Nat'l Golf Props.*, 2003 WL 23018761, at *1 ("[The PSLRA] does not require Lead Plaintiffs to have standing to assert all claims, only that they have the greatest financial stake in the action."); *see also Hevesi v. Citigroup Inc.*, 366 F.3d 70, 83 n.13 (2d Cir. 2004) (rejecting as contrary to the PSLRA any rule requiring that lead plaintiff has standing to bring every claim).

(9th Cir. 2000). "Adherence to these principles is especially important in the context of the PSLRA . . . . In this technical and demanding corner of the law, the drafting of a cognizable complaint can be a matter of trial and error." *Eminence Capital, L.L.C. v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003) (*per curiam*); *accord In re S. Pac. Funding Corp. Sec. Litig.*, 83 F. Supp. 2d 1172 (D. Or. 1999).

Dated: September 17, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, KAYE A. MARTIN, do hereby certify that on this 17th day of September, 2007, true and correct copies of the foregoing

> Lead Plaintiff's Opposition to Motion to Dismiss Filed by Defendants Connetics Corp., John L. Higgins, Lincoln Krochmal, C. Gregory Vontz and Thomas G. Wiggans; and
>
> Declaration of David R. Stickney in Support of Lead Plaintiff's Opposition to Motion to Dismiss Filed by Defendants Connetics Corp., John L. Higgins, Lincoln Krochmal, C. Gregory Vontz and Thomas G. Wiggans.

were filed electronically. Those attorneys who are registered with the Electronic Case Filing ("ECF") System may access this filing through the Court's system, and notice of this filing will be sent to the parties by operation of the Court's ECF System. Attorneys not registered with the Court's ECF system will be duly and properly served via facsimile and/or Federal Express (as indicated on the attached Service List), in accordance with the Federal Rules of Civil Procedure and the Court's Local Rules.

/s/ Kaye A. Martin
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Case No.: 07-02940

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